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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,263	09/28/2001	Timothy O'Brien	D6415	5220

7590 10/22/2004

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/967,263

Applicant(s)

O'BRIEN ET AL.

Examiner

Susan Ungar

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 03 September 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1, 2 and 5.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
10. ☐ Other: _____

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

Susan
SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

Susan Ungar
Primary Examiner
Art Unit: 1642

Continuation of 2. NOTE: The amendment of claim one to recite monoclonal antibody 4D5 raises a new 35 USC 112, first paragraph issue as drawn to claim 1, that is that no deposit information has been submitted for antibody 4D5. Further the amendment of the claim to recite Herceptin raises a 112 second paragraph issue because the term Herceptin is a trademark and the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Continuation of 5. does NOT place the application in condition for allowance because:

The arguments drawn to the 35 USC 112, first paragraph rejection of claims 1-2 are moot since the claims have not been entered.

If the amendment were to be entered, claims 1, 2, 5 would remain rejected under 35 USC 103 for the reasons previously set forth in the paper mailed November 5, 2003, section 10, pages 14-17.

Applicant argues that the invention instant invention differs greatly from the invention of Bookman et al, Berchuck et al, Saffari et al and Wang et al because in Bookman et al, only 3 of 41 patient achieved an objective response and only one had a complete response while the other two had partial response and in view of these results, a person having ordinary skill in this art would certainly consider this a statistically insignificant random effect and would not have a reasonable expectation that uterine serous papillary carcinoma could be treated with HERCEPTIN.

Applicant reiterates and expands arguments drawn to Bookman et al. These arguments have been considered and have not been found persuasive for the reasons of record. Applicant further argues that Berchuck et al, Saffari et al and Wang et al only analyzed a small number of uterine serous papillary carcinoma samples and none teach that HER-2/neu is uniformly over-expressed in every uterine serous papillary carcinoma and therefore could be targeted to successfully treat the disease and the teaching of the four combined references do not provide a reasonable expectation of success in treating these patients with HERCEPTIN. The argument has been considered but has not been found persuasive. Given that those of ordinary skill in the art know that HERCEPTIN treatment is drawn to those who overexpress Her-2/neu, given that it was known in the art that a subset of uterine serous papillary carcinoma patients over-express HER-2/neu, it would be obvious, as set forth in the first action on the merits, to treat that subset of uterine serous papillary carcinoma patients with HERCEPTIN and for the reasons of record, one would have a reasonable expectation of success. In addition, the rejection is not based on the combination of Bookman et al and Verchuck et al, Saffari et al and Wang et al. It is noted that Applicant has not addressed the issues raised drawn to the combination of Baselga et al, Agus et al of record, Berchuck et al, Saffari et al and Wang et al and Pegram et al. Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Finally, Applicants assert that obviousness requires that the prior art relied upon fairly teach or suggest all of the element of the instant invention and that an incentive or motivation be present in the prior art to produce the claimed invention. The argument has been considered but has not been found persuasive because the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981) and for the reasons of record the claimed invention is obvious over the combined prior art.